UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL MATERIALS IN THE POSSESSION OF THIRD PARTY VALISURE LLC

Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, "the ZHP Defendants") respectfully request that the Court compel third party Valisure LLC ("Valisure") to respond to a narrowly targeted subpoena seeking limited, essential information related to Valisure's June 13, 2019 citizen petition to the FDA ("the Citizen Petition"). Specifically, the ZHP Defendants request that Valisure be required to provide the National Drug Code ("NDC") identification numbers for the samples of valsartan product identified in the Citizen Petition as being manufactured, distributed, marketed and/or sold by Novartis. This information is readily available to Valisure, will not be burdensome to produce, and is relevant to the merits of this litigation.

As set forth below, a number of Plaintiffs' experts have recently disclosed opinions that Novartis's brand-name valsartan products, Diovan and Exforge, do not contain NDMA or NDEA – and that the presence of any level of these nitrosamines in generic valsartan products therefore renders them adulterated under FDA standards.[1] The Citizen Petition, however, expressly states that Valisure found NDMA in Novartis's valsartan. As a result, Valisure should be required to identify the NDC numbers for the Novartis samples it tested so that the ZHP Defendants, and other Defendants, can fully and fairly test the validity of Plaintiffs' experts' opinions.

BACKGROUND

On June 13, 2019, Valisure submitted a Citizen Petition to the FDA that included the results of Valisure's testing of certain lots of valsartan-containing drugs ("VCDs") for the potential presence of NDMA. The Citizen Petition showed detectable levels of NDMA in the majority of samples identified as Novartis valsartan product, including a level of 17 nanograms of NDMA in a 40 mg Novartis tablet. (*See* Valisure Citizen Petition at Appendix A, ECF No. 1984-1.)

[1] The ZHP Defendants and their experts strongly disagree with the assertion that generic valsartan is "adulterated" regardless of whether Diovan and/or Exforge contain these nitrosamines. Because Plaintiffs' experts expressly tie their adulteration opinions to the absence of nitrosamines in Novartis's brand-name valsartan, however, the ZHP Defendants are entitled to information capable of confirming whether NDMA has been found in those brand-name medications.

The Special Master has previously recognized that Valisure's identification of NDMA in Novartis product is relevant to Plaintiffs' claims. On July 25, 2022, the Court entered an order compelling Plaintiffs' expert Dr. Ron Najafi, whose laboratory validated some of the testing underlying Valisure's Citizen Petition, to produce a variety of materials related to such testing. (*See* Special Master Order No. 68 at 6, ECF No. 2137.) As the Special Master explained, Plaintiffs and Dr. Najafi have taken the position that: (1) generic valsartan manufacturers "must demonstrate that their active ingredient(s) are the same as the Reference Listed Drug ('RLD') and have identical strength, quality, purity, potency (and where applicable, other characteristics) as the RLD"; and (2) generic "Valsartan containing NDMA or NDEA (nitrosamines) is not the same and/or the chemical equivalent of its RLDs," Diovan and/or Exforge. (*Id*. at 1-2.) According to the Special Master's order, this assertion "is based upon the assumption that the RLDs 'contain zero NDMA and zero NDEA.'" (*Id*. at 2.) Thus, the "presence of nitrosamines in the RLDs would undermine" Plaintiffs' position that generic valsartan products are "not the same as the RLDs." (*Id*.) Because Dr. Najafi testified that he was involved in validating the testing underlying the Citizen Petition, the Special Master ordered Dr. Najafi and his lab to produce materials relating to testing on any valsartan drug substance or drug product. (*Id*. at 6.) In response to the Special Master's order, Dr. Najafi's laboratory produced a limited

amount of materials, none of which identified the specific Novartis valsartan products that were found to include NDMA.

On October 31, 2022, Plaintiffs submitted additional expert reports, many of which included opinions that the generic valsartan products manufactured and sold by Defendants were adulterated at the time of sale under FDA standards because Diovan and/or Exforge do not contain NDMA or NDEA. (*See, e.g.*, Expert Report of Laura M. Plunkett, Ph.D., DABT ("10/31/22 Plunkett Rep.") at 4, Oct. 31, 2022 ("Diovan (the Reference Listed Drug 'RLD' for valsartan) should not contain NDMA or NDEA. Therefore, valsartan with NDMA or NDEA impurities [is] not pharmaceutically equivalent or therapeutically equivalent to the RLD due to the presence of NDMA or NDEA.") (footnote omitted); Expert Report of Susan Bain, DRSc ("10/31/22 Bain Rep.") at 75, Oct. 31, 2022 ("As a result of the CGMP violations . . . [Defendants] sold pills that were represented to be the approved form of valsartan, but in fact were not – instead, they were valsartan containing NDMA, and in some also NDEA. Those pills did not match the description in the original NDA for the brand RLD Diovan or Exforge, the DMF, the applicable ANDAs, the pharmacopeias, or the designation on the label as USP Valsartan. The pills were not the approved formulation of Valsartan and were adulterated by definition."); Expert Report of Ramin (Ron) Najafi, Ph.D. ("10/31/22 Najafi Rep.") at 29, Oct. 31, 2022 ("The referenced listed drug for valsartan is Diovan which

does not contain NDMA or NDEA. Defendants' valsartan containing products were not the generic, pharmaceutical, therapeutic and chemical[] equivalent of Diovan or Exforge because they contained NDMA and NDEA.") (relevant pages of reports attached collectively as Ex. 1 to Cert. of Jessica Davidson Miller ("Miller Cert.")).)

Following the submission of Plaintiffs' expert reports, counsel for the ZHP Defendants issued a third-party subpoena to Valisure on December 14, 2022. (*See* Defs.' Notice of Subpoena, Subpoena to Produce Docs., Information, or Objects or to Permit Inspection of Premises in a Civil Action ("Valisure Subpoena"), and Attachment A (Dec. 14, 2022) (Ex. 2 to Miller Cert.).) The attachment to the subpoena requested the production of only one limited category of materials: "Documents sufficient to identify the NDC of all Novartis Product referenced in the Citizen Petition submitted by Valisure to FDA." (Attachment A to Valisure Subpoena at 2.)

On December 21, 2022, counsel for Plaintiffs objected to the subpoena as "out of time" based on the assertion that fact discovery in this proceeding is closed. (Email from Conlee S. Whiteley to Christopher J. Santoli (Dec. 21, 2022) (Ex. 3 to Miller Cert.).) On December 26, 2022, counsel for Valisure objected to the subpoena, arguing that it is "inconsistent with Valisure's obligations under the Federal Rules of Civil Procedure," "requires the disclosure of privileged or

otherwise protected information or communications," and "imposes undue costs on a third party." (Valisure Objection Letter (Dec. 26, 2022) (Ex. 4 to Miller Cert.).) Valisure further stated that "[s]ubject to the foregoing objections, Valisure is aware that plaintiffs in the above referenced case are challenging this subpoena and at this time Valisure defers to the Court or other resolution of this matter." (*Id*.)

ARGUMENT

"The scope of discovery in federal litigation is broad," such that "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." *See OMS Invs., Inc. v. Lebanon Seaboard Corp.*, No. 08-2681 (AET), 2008 WL 4952445, at *1 (D.N.J. Nov. 18, 2008) (quoting Fed. R. Civ. P. 26(b)(1)). Rule 26(b) is "construed liberally in favor of disclosure," and relevance encompasses "any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Gov't Emps. Ins. Co. v. Trnovski*, No. 16-4662 (CCC), 2018 WL 5281424, at *2-3 (D.N.J. Oct. 23, 2018) (citation omitted).

"Discovery sought via a subpoena issued pursuant to Rule 45," including third-party subpoenas, "must fall within the scope of discovery permissible under Rule 26(b)." *Wyeth v. Abbott Lab'ys*, No. 08-1021 (JAP), 2011 WL 2429318, at *4 (D.N.J. June 13, 2011). While the party "'responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense

on a person subject to the subpoena' . . . it is the party claiming undue burden that must establish" its existence in order to avoid compliance. *Id.* (citation omitted); *see also OMS Invs., Inc*., 2008 WL 4952445, at *2 (the party resisting a third-party subpoena "has the heavy burden of demonstrating the unreasonableness or oppressiveness of the subpoena"). Courts evaluating the reasonableness of third-party subpoenas look to a number of factors, including: "(1) the party's need for the production; (2) the nature and importance of the litigation; (3) relevance; (4) the breadth of the request for the production; (5) the time period covered by the request; (6) the particularity with which the documents are described; and (7) the burden imposed on the subpoenaed entity." *OMS Invs., Inc*., 2008 WL 4952445, at *3. All of these factors strongly favor compelling Valisure to provide the limited information requested, given its relevance to both Plaintiffs' theory of the case and the validity of their experts' opinions.

First, the initial three factors considered by courts weigh in favor of granting the motion to compel because the ZHP Defendants have substantial need for information confirming the name of the Novartis valsartan product(s) identified as containing NDMA – and that information is highly relevant to this litigation. While "the standards for nonparty discovery require a stronger showing of relevance than for simple party discovery," courts in this district have recognized that "[t]his distinction" is of little difference where, as here, the relevance of the

discovery sought is clear. *Hancock v. Credit Pros Int'l Corp.*, No. 2:20-cv-02826-SRC-CLW, 2021 WL 2948154, at *8 n.16 (D.N.J. July 13, 2021) (citation omitted) ("[T]he [c]ourt sees no reason to conclude that this information falls within the category of materials sufficiently relevant to mandate production by a party but not relevant enough to warrant nonparty production."); *see also Biotechnology Value Fund, L.P. v. Celera Corp.*, No. 14-4046 PGS, 2014 WL 4272732, at *3 (D.N.J. Aug. 28, 2014) (granting motion to compel response to third-party subpoena where the information sought was relevant to "a central issue in the underlying case").

The Special Master has already recognized that information relating to Valisure's testing of Novartis valsartan for NDMA is clearly relevant to this litigation. As the Special Master explained in compelling Dr. Najafi to produce materials on this topic, Dr. Najafi's opinion that VCDs with trace amounts of NDMA or NDEA are not chemically equivalent to the RLDs is based upon the assumption that Diovan and Exforge "contain zero NDMA and zero NDEA.'" (Special Master Order No. 68 at 1-2, ECF No. 2137 (citation omitted).) Accordingly, the Special Mater recognized that the detection of NDMA in samples of Diovan or Exforge would "undermine" the validity of Dr. Najafi's opinions – and therefore materials related to Valisure's testing of Novartis product "are clearly relevant to" Plaintiffs' claims. (*Id.* at 2, 5.)

Since that order was issued, Dr. Najafi and other experts proffered by Plaintiffs have issued new reports doubling down on their theory that any generic VCDs containing trace amounts of NDMA or NDEA were adulterated at the time of sale because the Novartis RLD was free of nitrosamines. (*See, e.g.*, 10/31/22 Najafi Rep. at 29; 10/31/22 Plunkett Rep. at 4; 10/31/22 Bain Rep. at 75.) While the ZHP Defendants and their experts dispute that generic VCDs were adulterated regardless of the nitrosamine content of the Novartis RLD, they are entitled to challenge the basic premise of Plaintiffs' experts' opinions: that Diovan and Exforge were nitrosamine-free. The NDC numbers for the Novartis valsartan in which NDMA was identified will allow the ZHP Defendants to conclusively establish whether those products were Diovan and/or Exforge. This information is especially important given that Plaintiffs have previously suggested that the Novartis product tested by Valisure was not the RLD, but a generic valsartan product. (*See* Pls.' Br. in Opp'n to Defs.' Mot. to Compel Produc. of Testing & Other Materials in Possession of Class Expert, Dr. Ron Najafi at 4, ECF No. 2023 ("Novartis did sell generic valsartan in Europe. . . . And Valisure's citizen petition refers to the Novartis pills by their generic names— valsartan and valsartan-HCTZ, and not by their brand names—Diovan and Exforge.").) As Defendants have previously explained, Plaintiffs' argument is illogical because Novartis's generic valsartan was not sold in the United States, and Valisure would not have included

test results related to foreign valsartan in a Citizen Petition requesting an FDA recall of valsartan available in this country. (*See* Br. in Supp. of Defs.' Mot. to Compel Produc. of Testing & Other Materials in Possession of Class Expert, Dr. Ron Najafi at 15, ECF No. 2013-1.) Because Plaintiffs have sowed confusion by disputing that the Novartis test results reported in the Citizen Petition relate to Diovan or Exforge, it is essential that Valisure disclose the NDC identification numbers for the Novartis samples it tested.

Second, the remaining factors considered by courts in evaluating third-party subpoenas similarly support granting the motion to compel because the ZHP Defendants' subpoena: (1) is extremely limited in breadth and temporal scope; (2) describes the information requested with particularity; and (3) would impose minimal, if any, burden on Valisure. The ZHP Defendants' subpoena seeks a single, specific category of information: documents that would allow the ZHP Defendants to identify the NDC numbers for the Novartis products that were tested by Valisure and listed in its Citizen Petition. As noted above, Valisure has objected to the subpoena on the ground that compliance would impose undue costs on it as a third party. But a simple letter from Valisure providing the NDC numbers for the tested Novartis samples – which should be readily available in Valisure's testing records – would suffice to fulfill the ZHP Defendants' request. As a result, responding to the subpoena would cost Valisure virtually nothing.

Further, any minimal burden to Valisure is far outweighed by the importance of the information. *See Wyeth*, 2011 WL 2429318, at *8 (finding that "[b]are allegations of burden will not suffice" to defeat a third-party subpoena where the information requested is "entirely relevant to" the party's claims and the subpoena is "appropriately limited") (citation omitted); *Biotechnology Value Fund*, 2014 WL 4272732, at *4 ("[T]he [c]ourt finds that [p]laintiffs' narrowed request does not impose an undue burden on [the third party], since the request is tailored to provide [p]laintiffs with information that goes directly to the core of the underlying case" and the third party "provide[d] only conclusory claims that d[id] not adequately demonstrate any undue burden . . . .").

There is also no basis for Valisure's objection that providing the NDC numbers for the Novartis products it tested would require the disclosure of privileged or other protected information. NDC numbers are generally publicly available and therefore are not protected information. *See* National Drug Code Directory, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory (last updated July 22, 2022). In any event, the Protective Order in place in this proceeding would allow Valisure to designate documents as confidential. Thus, even if materials reflecting Novartis NDC numbers were in some way proprietary, they would be protected from public disclosure. And Valisure has not identified any privileged communications that

would be threatened by providing the NDC numbers for samples it tested for purposes of submitting a public filing to the FDA.

Nor would granting the ZHP Defendants' motion to compel impose any burden on Plaintiffs. While Plaintiffs have taken the position that the subpoena is "out of time" because fact discovery has closed, there is no provision in the CMO that prohibits seeking documents from a third party past a certain date. (*See* CMO No. 23, ECF No. 863.) Further, the information sought is directly relevant to expert discovery, which is currently ongoing. As noted above, at least three of Plaintiffs' experts recently provided expert reports in which they opined that Novartis's Diovan and/or Exforge products are free of nitrosamines. (*See, e.g.*, 10/31/22 Najafi Rep. at 29; 10/31/22 Plunkett Rep. at 4; 10/31/22 Bain Rep. at 75.) These experts are scheduled to be deposed over the course of the next several weeks. It is critical that Valisure be compelled to promptly disclose the NDC numbers for the Novartis products in which NDMA was identified so that the ZHP Defendants and other Defendants can fully and fairly test the validity of Plaintiffs' experts' opinions.

CONCLUSION

For the reasons set forth above, the ZHP Defendants respectfully requests that the Court enter an order compelling Valisure to comply with the ZHP Defendants' December 14, 2022 subpoena by identifying the NDC numbers for the

Novartis valsartan products that Valisure tested in connection with its Citizen Petition to the FDA.

Dated: January 4, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 4, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson Miller*
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